PATENT COOPERATION TREATY

SIGPCTAPTO 29 DEC 2004

PCT/EP2003/006851

# **PCT**

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference   |  |   |   |
|---|--|---|---|
| 30A-91 480  | FOR FURTHER ACTIO  | N See Notifi<br>Preliminary                     | ication of Transmittal of International Examination Report (Form PCT/IPEA/416)      |
| International application No.   | International filing date (day   | y/month/year)                                   | Priority date (day/month/year)  |
| PCT/EP2003/006851   | 27 June 2003 (27.0   | 06.2003)  | 01 July 2002 (01.07.2002)   |
| International Patent Classification (IPC) or n A61K 31/48   | ational classification and IPC   |   |   |
| Applicant   |  |   |   |
|   | WANK, Rudo   | olf   |   |
| This international preliminary examinand is transmitted to the applicant according to the accordi | nation report has been prepare cording to Article 36.  | ed by this Intern                               | ational Preliminary Examining Authority   |
| 2. This REPORT consists of a total of   | 5 sheets, includ   | ing this cover sl                               | neet.   |
| This report is also accompanie amended and are the basis for 70.16 and Section 607 of the A   | d by ANNEXES, i.e., sheets of<br>this report and/or sheets conta<br>Administrative Instructions un | of the description ining rectificated the PCT). | n, claims and/or drawings which have been ions made before this Authority (see Rule |
| These annexes consist of a total  |  | ·   |   |
| 3. This report contains indications relation  | ng to the following items:   |   |   |
| I Basis of the report   |  |   |   |
| II Priority   |  |   |   |
| III Non-establishment of  | opinion with regard to novelt  | y, inventive step                               | and industrial applicability  |
| IV Lack of unity of inven   | tion   |   |   |
| V Reasoned statement un citations and explanati   | nder Article 35(2) with regard ons supporting such statemen  | to novelty, inve                                | entive step or industrial applicability;  |
| VI Certain documents cité   |  |   |   |
| VII Certain defects in the i  | nternational application   |   |   |
| VIII Certain observations of  | n the international application  |   |   |
|   |  |   |   |
| Date of submission of the demand  | Date of  | completion of t                                 | his report  |
| 23 January 2004 (23.01.20   |  |   | ober 2004 (28.10.2004)  |
| Name and mailing address of the IPEA/EP   | Authori  | zed officer                                     |   |
| acsimile No.  | Telepho  | ne No.  |   |
| orm PCT/IDEA/400 / 1 3 4m 4   |  |   |   |

Translation

International application No. PCT/EP2003/006851

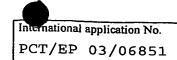
|  | report   |
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| the inte   | to the elements of the international application:*   |
|  | ernational application as originally filed   |
| the des  | scription:   |
| pages  | 1-8 , as originally filed  |
| pages  | , filed with the demand  |
| pages  | , filed with the letter of   |
| the cla  |  |
| E-3  | as originally filed  |
| pages  | , as amended (together with any statement under Article 19   |
| pages<br>pages   | filed with the demand  |
| pages  | 1-16 , filed with the letter of 30 July 2004 (30.07.2004)  |
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| pages pages pages pages pages  2. With regard the internation These eleme the late the late or 55.  3. With regard preliminary conta filed to furnis furnis The  | to the language, all the elements marked above were available or furnished to this Authority in the language in whomat application was filed, unless otherwise indicated under this item.  In the subsequently furnished to this Authority in the following language which anguage of a translation furnished for the purposes of international search (under Rule 23.1(b)).  In the subsequently to this Authority in the following language anguage of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 at 3.3).  In the subsequented and/or amino acid sequence disclosed in the international application, the international examination was carried out on the basis of the sequence listing:  In the international application in written form.  It together with the international application in computer readable form.  It is subsequently to this Authority in computer readable form.  It is statement that the subsequently furnished written sequence listing does not go beyond the disclosure in antional application as filed has been furnished.  It is the letter of the with the demandance of the subsequence listing in the international application as filed has been furnished.  It is the letter of this Authority in computer readable form is identical to the written sequence listing and the written sequence listing the written sequence listing the written sequence listing to the written sequence listing the written sequence listing the written sequence listing to the written sequence listing to the written sequence listing the written seque |



International application No.

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| III. Non-          | establishment of opinion with regard to novelty, inventive step and industrial applicability  |
|--------------------|---|
| 1. The q<br>indust | questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be rially applicable have not been examined in respect of:                                     |
|                    | the entire international application.   |
| $\boxtimes$        | claims Nos  |
| becaus             | se: <sub>.</sub>  |
|                    | the said international application, or the said claims Nos  |
|                    | the description, claims or drawings (indicate particular elements below) or said claims Nosare so unclear that no meaningful opinion could be formed (specify):   |
| $\boxtimes$        | the claims, or said claims Nos. 1, 2, 4-16 are so inadequately supported by the description that no meaningful opinion could be formed.   |
| $\boxtimes$        | no international search report has been established for said claims Nos   |
| 2. A mean sequen   | ningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid acceleration in the standard provided for in Annex C of the Administrative Instructions: |
|                    | the written form has not been furnished or does not comply with the standard.   |
|                    | the computer readable form has not been furnished or does not comply with the standard.   |



Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: BOX III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The subject matter of claims 1, 2 and 4-16 was only partially searched (see extra sheet PCT/ISA/210 in the international search report) because of insufficient disclosure and support by the description (PCT Articles 5 and 6).

The applicant is advised that claims or parts of claims relating to inventions in respect of which no international search report has been established cannot normally be the subject of an international preliminary examination (PCT Rule 66.1(e)). In its capacity as International Preliminary Examining Authority the EPO generally will not carry out a preliminary examination for subjects that have not been searched. This also applies to cases where the claims were amended after receipt of the international search report (PCT Article 19) or where the applicant submits new claims in the course of the procedure under PCT Chapter II.

The functional definition "dopamine receptor agonists" (claim 1) is not supported over its entire scope (PCT Articles 5 and 6) because the applicant shows the claimed therapeutic effect only for bromocriptine.

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| <b>v</b> . | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |  |  |
|------------|---|--|--|
| 1.         | Statement   |  |  |

| Statement                     |        |                               |     |
|-------------------------------|--------|-------------------------------|-----|
| Novelty (N)                   | Claims | 1-16                          | YES |
|                               | Claims |                               | NO  |
| Inventive step (IS)           | Claims | 6                             | YES |
|                               | Claims | 1-5, 7-16                     | NO  |
| Industrial applicability (IA) | Claims | 1-16 (see supplemental sheet) | YES |
|                               | Claims |                               | NO  |

2. Citations and explanations

This report makes reference to the following documents:

D1: WO 99/47133 A (RESNICK MARK G; SOMERSET

PHARMACEUTICALS INC (US)), 23 September 1999 (199909-23)

D2: US-A-5 792 748 (MEIER ALBERT H ET AL), 11 August 1998 (1998-08-11)

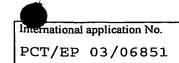
D3: US 2001/049350 A1 (CINCOTTA LOUIS ET AL), 6 December 2001 (2001-12-06)

### Novelty - PCT Article 33(2)

WO 99/47133 (D1) shows selegiline-containing preparations for the topical treatment of wounds, burns and photodamaged skin. The subject matter of independent claim 1 is novel over D1 because D1 does not mention the therapy of skin tumours and warts.

US 579 2748 (D2) discloses the inhibition of neoplasia, including melanomas (see the claims), by modulation of the prolactin level. Bromocriptine can be used with an increased prolactin level. Bromocriptine is systemically administered.

US 2001/049350 (D3) describes the use of bromocriptine for



the photodynamic therapy of tumours, for example in the case of skin cancer. Bromocriptine is systemically used.

Since D2 and D3 disclose only the systemic administration of bromocriptine, the subject matter of independent claim 1 is novel over the disclosure of D2 and D3.

### Inventive step - PCT Article 33(3)

Document D2 should be regarded as the closest prior art. In that document, neoplasia, including melanomas, is systemically treated with bromocriptine. However, it would be obvious for a person skilled in the art to administer bromocriptine topically to skin tumours, especially since the topical administration of dopamine receptor agonists in the case of skin diseases is already known (D1).

The subject matter of the dependent claims appears to relate only to well known alternatives. For this reason, an inventive step cannot at present be acknowledged in the subject matter of claims 1-5 and 7-16.

Documents D1-D3 do not contain any indication of the topical treatment of warts with bromocriptine.

### Industrial applicability - PCT Article 33(4)

In the PCT Contracting States, there are no uniform criteria for assessing the industrial applicability of Claims 1-16 in their present form. Patentability can also depend on the wording of the claims. The EPO, for example, does not recognise the industrial applicability of claims to the use of a compound in a medical treatment; it does, however, allow claims to the first use of a known compound in a medical treatment or to the use of such a compound in the manufacture of a drug for a new medical treatment.